

## **REMARKS**

In the Office Action mailed April 13, 2007, Claims 1-20, 25-27, 30-31, 36-38 were withdrawn as a result of a restriction requirement. Additionally, Claim(s) 21 (in part), 22-24, 28-29, 32 (in part), 33-35, and 39-40 were rejected under 35 U.S.C. 103(a). This rejection was discussed in applicant's arguments filed on 7/9/2007 and maintained in the Office Action mailed September 28, 2007. In response to this latter, final rejection Claims 21 and 32 have been amended and Claims 28-29 and 39-40 have been withdrawn in this Request for Continued Examination. Also, in Claims 21 and 32, the term "preventing" has been eliminated and the term "fasting" has been eliminated from Claim 32.

Claim 21 has also been amended to reflect the fact that the term "fat maldistribution" has been changed to the more restrictive, "subcutaneous fat loss." Similarly Claim 32 has been amended to read more restrictively on a method for treating or normalizing hyperlipidemia coincident with subcutaneous fat loss and body wasting." Support for these amendments can be found in ¶0010 of the instant application, which states, "The physical changes associated with the HIV/ART lipodystrophy syndrome can be divided into two major types, both of which involve an abnormal or maldistribution of body fat: lipoatrophy or fat wasting and lipohypertrophy or fat accumulation. An increase in abdominal girth is a common complaint in patients, while thinning of the extremities is also frequently seen, often with prominence of the veins in the arms and legs (cabling) due to subcutaneous fat loss. A substantial proportion of patients report increased wrinkling of the skin with a loss of subcutaneous tissue in the cheeks and around the nose and lips.

Further restrictions to Claims 21 and 32 include the limitation of the thiol-containing compounds to only N-acetylcysteine and the withdrawal of Claims 28-29 and 39-40.

Claims 21-24, and 32-35 remain pending in the present application, and Applicants respectfully submit that these claims are in condition for allowance.

35 U.S.C. § 103(a) Rejection:

*The McCleary Application (US Patent Application 2002/0132219A1)*

The instant pending claims are directed to a method for treating normalizing subcutaneous fat loss or hyperlipidemia coincident with subcutaneous fat loss and body wasting resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering triglyceride of conjugated linoleic acid and N-acetylcysteine. The Examiner has rejected Claim(s) 21 (in part), 22-24, 28-29, 32 (in part), 33-35, and 39-40 under 35 U.S.C. 103(a) as being allegedly unpatentable over McCleary (US Patent Application 2002/0132219A1, hereinafter “McCleary”). As cited by the Examiner, McCleary teaches:

1. [in Abstract] A nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid for modulating nutrient composition in a human.
2. [¶0002] Disorders of nutrient partition include obesity (fat maldistribution) and hyperlipidemia.
3. [¶0006 to ¶0007] More particularly, it is desirable to provide a means for modulating aberrant pathways of nutrient partitioning so as to avoid excessive fat storage, to promote oxidation of fat, and reduce fat levels.

4. [¶0010] McCleary also discloses specifically triglyceride of conjugated linoleic acid.

5. [¶0023] McCleary also teaches that fat synthesis and storage are diminished resulting in a fall in the intracellular fat content of the liver, pancreas, and skeletal muscle as well as a fall in visceral fat and total body fat stores accompanied by a decrease in individual fat cell volume.

6. [Table 1] Preferred amounts for CLA are 50 mg to 20 g and for alpha-lipoic acid are 25 mg to 2 g.

With regard to points 1 and 6, Claims 21 and 32 have been amended to read only on N-acetylcysteine as the thiol containing compound and Claims 28-29 and 39-40 have been withdrawn. This eliminates lipoic acid and other thiol-containing compounds from the method.

As noted by the Examiner, McCleary fails to disclose fat maldistribution or hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection in a subject. Specifically, in ¶0002 McCleary does not define obesity parenthetically as fat maldistribution and the term “fat maldistribution” never appears in the application. The term obesity is not defined in McCleary, but among researchers in the field and those skilled in the art, Stedman’s Medical Dictionary is considered the reference standard for defining medical terms. Stedman’s Medical Dictionary [26<sup>th</sup> edition] defines obesity as, “An abnormal increase of fat in the subcutaneous connective tissues.” Note that in the context of this definition, the increased fat accumulation in obesity occurs in the subcutaneous tissue layer as opposed to only in the visceral location. This teaches away from the fat maldistribution or lipodystrophy seen in HIV-1 patients treated with

HAART, as those persons loose subcutaneous fat as noted in the instant application (see ¶0010 and ¶0051) and the purpose of the invention is to increase subcutaneous fat (see ¶0024, 0025 and 0035).

Further, unlike McCleary the instant invention does not reduce body weight. ¶0051“... the compositions provided herein do not function to reduce body weight or indiscriminately reduce body fat. Since wasting, or loss of body weight, is a constant concern in HIV patients, formulations that would cause a loss of body weight would be contraindicated. Further, the process of reversing fat maldistribution as seen in HIV/ART requires subcutaneous fat deposition in concert with visceral fat loss--a process not consistent with general fat loss.”

Additionally, in Example 1 (¶0086) it is stated, “Significant differences are noted in fat distribution as determined by BIA and CT in the test subjects the six- and twelve-week examinations. Waist circumferences decrease in concert with increases in mid-forearm, mid-bicep and thigh circumferences. Body weights do not change in either group and percent body fat is not altered with the test material relative to the placebo.” McCleary is a self-described weight loss program [¶0024] that functions to decrease total body fat and decrease appetite [¶0025]. The present invention does not function to reduce body weight or indiscriminately reduce body fat.

It is thus the Applicant’s assertion that McCleary or a modification of McCleary no longer teaches or suggests any elements of the present invention. Specifically, support for this conclusion comes from the following:

1. Applicants have removed lipoic acid or other thiol-containing compounds from the methods by restricting the thiol-containing compound to N-acetylcysteine.
2. Obesity as defined by Stedman's Medical Dictionary [26<sup>th</sup> edition] is, "An abnormal increase of fat in the subcutaneous connective tissues." This teaches away from the fat maldistribution or lipodystrophy seen in HIV-1 patients treated with HAART, as those persons loose subcutaneous fat.

## CONCLUSION

In view of the foregoing, the Applicants assert that Claims 21-24, and 32-35 of the present application present allowable subject matter and the allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone Dr. John G. Babisch so that such issues may be resolved as expeditiously as possible.

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Respectfully submitted,

Bionexus, Ltd.



John G. Babisch, Ph.D.  
jgb7@cornell.edu  
Cornell Technology Park  
30 Brown Road  
Ithaca, NY 14850  
Telephone: (607) 266-9492  
Facsimile: (607) 266-9481